

Claims

1. A pharmaceutical formulation comprising olanzapine or a pharmaceutically acceptable salt thereof as an active ingredient, obtainable by homogeneously mixing (a) olanzapine or a pharmaceutically acceptable salt thereof with (b) a monosaccharide and/or oligosaccharide and/or a reduced or oxidised form thereof, (c) a polysaccharide and optionally one or more additional excipients, followed by a direct compression of the mixture into tablets in the absence of any solvent.
2. The pharmaceutical formulation of claim 1 comprising 40 to 80 weight % of the component (b).
3. The pharmaceutical formulation of any one of claims 1 to 2 comprising 10 to 40 weight % of the polysaccharide.
4. The pharmaceutical formulation of any one of claims 1 to 3 additionally comprising (d) up to 15 weight % of a disintegrant.
5. The pharmaceutical formulation of any one of claims 1 to 4 additionally comprising (e) 5 to 20 weight % of a binder.
6. The pharmaceutical formulation of any one of claims 1 to 5 additionally comprising (f) 0.25 to 5 weight % of a lubricant.
7. The pharmaceutical formulation of any one of claims 1 to 6 additionally comprising (g) 0.1 to 0.5 weight % of a glidant.

8. The pharmaceutical formulation of any one of claims 1 to 7, wherein the component (b) is selected from the group consisting of lactose, sucrose, dextrose, sorbitol, mannitol, lactitol, and mixtures thereof.
9. The pharmaceutical formulation of claim 8, wherein the component (b) is lactose.
10. The pharmaceutical formulation of any one of claims 1 to 9, wherein the polysaccharide is selected from the group consisting of starch, cellulose, and mixtures thereof.
11. The pharmaceutical formulation of claim 10, wherein the polysaccharide is cellulose.
12. The pharmaceutical formulation of claim 11, wherein a mixture of 20 to 30 weight % of cellulose and 70 to 80 weight % of lactose is used as the components (b) and (c).
13. The pharmaceutical formulation of claim 12 comprising
70 to 90 weight % of a mixture of 20 to 30 weight % of cellulose and 70 to 80 weight % of lactose;
8 to 12 weight % of a binder;
3 to 10 weight % of a disintegrant;
0.3 to 2 weight % of a lubricant; and
0.2 to 0.4 weight % of a glidant.
14. The pharmaceutical formulation of any one of claims 1 to 13 comprising olanzapine as the only pharmaceutically active ingredient.

15. The pharmaceutical formulation of any one of claims 1 to 14 having the form of an uncoated tablet.
16. A process for preparing a stable pharmaceutically solid oral formulation according to any one of claims 1 to 15 comprising combining (a) olanzapine or a pharmaceutically acceptable salt thereof with (b) a monosaccharide and/or oligosaccharide and/or a reduced or oxidised form thereof, (c) a polysaccharide and optionally one or more of components (d) to (g), followed by a direct compression of the mixture into tablets in the absence of any solvent.